

HIPAA Privacy Rule Checklists Section 164.512 – Public Policy Rationales

**Prepared by the
NCHICA Consent and Patients Rights Work Group
Privacy and Confidentiality Focus Group**

**Approved for Public Distribution
March 29, 2002**

HIPAA Privacy Rule Checklists Section 164.512 – Public Policy Rationales

I. Test for When Consent, Authorization or Agreement NOT Required

A covered entity may use or disclose protected health information without the consent, authorization or agreement of an individual if it satisfies **one** of the following:

[*Note:* When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.]

- a. ____ **Uses and Disclosures Required by Law.** A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law. *Note:* A covered entity must meet the requirements described below in subsection (c), (e), or (f) for uses or disclosures required by law.
- b. ____ **Uses and Disclosures for Public Health Activities.** A covered entity may use or disclose protected health information if either of the following is satisfied:
 - i. ____ The protected health information is **disclosed** to *one* of the following for the purposes described:
 - ____ A public health authority authorized by law to receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death; and the conduct of public health interventions;
 - ____ At the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;
 - ____ A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;
 - ____ A person subject to the jurisdiction of the FDA for *one* of the following purposes:
 - (a) To report adverse events, product defects or problems, or biological product deviations if the disclosure is made to the person required or directed to report such information to the FDA;
 - (b) To track products if the disclosure is made to a person required or directed by the FDA to track the product;
 - (c) To enable product recalls, repairs, or replacement; or
 - (d) To conduct post marketing surveillance to comply with requirements or at the direction of the FDA;
 - ____ A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by

law to notify such person as necessary in the conduct of a public health intervention or investigation; **or**

_____ An employer, about an individual who is a member of the employer's workforce, if:

- (a) The covered entity is a covered health care provider who is a member of the employer's workforce or who provides health care to the individual at the employer's request (1) to conduct an evaluation relating to medical surveillance of the workplace, or (2) to evaluate whether the individual has a work-related illness or injury;
- (b) The protected health information that is disclosed consists of findings concerning a work-related illness or injury or a workplace-related medical surveillance;
- (c) The employer needs such findings to comply with its federal and state law obligations to record such illness or injury or to carry out responsibilities for workplace medical surveillance; **or**
- (d) The covered health care provider provides written notice to the individual that protected health information relating to the medical surveillance of the workplace and work-related illnesses and injuries is disclosed to the employer (1) by giving a copy of the notice to the individual at the time the health care is provided, or (2) if the health care is provided on the employer's work site, by posting the notice in a prominent place at the location where the health care is provided.

ii. _____ Or, if the covered entity is also a public health authority, the protected health information is **used** in accordance with Section I.b.i, *above*.

c. _____ **Disclosures about Victims of Abuse, Neglect or Domestic Violence.** Except for reports of child abuse or neglect authorized in Section I.b, a covered entity may disclose protected health information if *each* of the following conditions are satisfied:

- i. _____ The protected health information concerns an individual whom the covered entity reasonably believes to be a victim of abuse, neglect, or domestic violence;
- ii. _____ The protected health information is disclosed to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence;
- iii. _____ The protected health information is disclosed:

_____ To the extent the disclosure is required by law and the disclosure complies with and is limited to the relevant requirements of such law;

_____ If the individual agrees to the disclosure; **or**

_____ To the extent the disclosure is expressly authorized by statute or regulation, and (1) the covered entity, in the exercise of professional judgment, believes the disclosure is necessary to prevent serious harm to the individual or other potential victims; *or* (2) if the individual is unable to agree due to incapacity, a law enforcement or other public official authorized to receive the report represents that the protected health information for which disclosure is sought is not intended to be used against the individual and that an immediate enforcement activity that

depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure; *and*

- iv. ____ The covered entity promptly informs the individual that such a report has been or will be made, **unless**:
- ____ The covered entity, in the exercise of professional judgment, believes informing the individual would place the individual at risk of serious harm; *or*
 - ____ The covered entity would be informing a personal representative, and the covered entity reasonably believes the personal representative is responsible for the abuse, neglect, or other injury, and that informing such person would not be in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.
- d. ____ **Uses and Disclosures for Health Oversight Activities.** A covered entity may disclose protected health information if *each* of the following conditions are satisfied:
- i. ____ The protected health information is *disclosed* to a health oversight agency, or *used* by a covered entity that is also a health oversight agency, for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of:
- ____ The health care system;
 - ____ Government benefit programs for which health information is relevant to beneficiary eligibility;
 - ____ Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; *or*
 - ____ Entities subject to civil rights laws for which health information is necessary for determining compliance.
- ii. ____ The following exception does not apply:
- (a) A health oversight activity does not include an investigation or other activity in which the individual is the subject of the investigation or activity and such investigation or activity does not arise out of and is not directly related to (1) the receipt of health care; (2) a claim for public health-related benefits; or (3) qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services.
- Note:* If a health oversight activity or investigation is conducted in conjunction with an oversight activity or investigation relating to a claim for non-health-related public benefits, the joint activity or investigation is considered a health oversight activity.
- e. ____ **Disclosures for Judicial and Administrative Proceedings.** A covered entity may disclose protected health information in the course of any judicial or administrative proceeding if the following conditions are satisfied:
- i. ____ The protected health information is disclosed either:
- ____ In response to a court order, to the extent that the protected health information is expressly authorized by the order; *or*

- _____ In response to a subpoena, discovery request, or other lawful process, that is not accompanied by a court order, if the covered entity receives satisfactory assurance that (a) reasonable efforts have been made to ensure that the subject of the requested protected health information has been given notice of the request, or (b) reasonable efforts have been made to secure a qualified protective order.
- ii. _____ *If the covered entity discloses information pursuant to a subpoena or discovery request based on reasonable efforts to give notice, it has done so only after receiving satisfactory assurances from the party seeking the information that reasonable efforts to give notice have been made (or after making the reasonable efforts to give notice *itself*), and the satisfactory assurances are in the form of a written statement and accompanying documentation demonstrating that:*
 - _____ The party requesting such information has made a good faith attempt to provide written notice to the individual;
 - _____ The notice included sufficient information about the litigation or proceeding in which the protected health information is requested to permit the individual to raise an objection to the court; *and*
 - _____ The time for the individual to raise objections to the court has elapsed, and (a) no objections were filed, or (b) all objections filed have been resolved, and the disclosures being sought are consistent with such resolution.
- iii. _____ *If the covered entity discloses information pursuant to a subpoena or discovery request based on reasonable efforts to secure a qualified protective order, it has done so only after receiving satisfactory assurances from the party seeking the information that reasonable efforts to secure a protective order have been made (or after making the reasonable efforts to secure a protective order *itself*), and the satisfactory assurances are in the form of a written statement and accompanying documentation demonstrating that:*
 - _____ The parties to the dispute giving rise to the request for information have agreed to a qualified protective order and have presented it to the court with jurisdiction; *or*
 - _____ The party seeking the protected health information has requested a qualified protective order from the court.

Note: For purposes of this Section, a “qualified protective order” means an order of a court or of an administrative tribunal or a stipulation by the parties to the litigation or administrative proceeding that (1) prohibits the parties from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested; and (2) requires the return to the covered entity or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding.

- f. _____ **Disclosures for Law Enforcement Purposes.** A covered entity may disclose protected health information for a law enforcement purpose to a law enforcement official if the following conditions are satisfied:
 - i. _____ **Pursuant to process and as otherwise required by law.** A covered entity discloses protected health information

- _____ As required by law; or
- _____ In compliance with, and as limited by,
 - (a) a court order or court-ordered warrant, or court-issued subpoena;
 - (b) a grand jury subpoena; or
 - (c) an administrative request, provided that (1) the information sought is relevant and material to a legitimate law enforcement inquiry; (2) the request is specific and limited in scope to the extent reasonably practicable; and (3) de-identified information could not reasonably be used. *Note:* These conditions may be satisfied by the administrative subpoena that, on its face, demonstrates that the applicable requirements have been met. [§ 164.514(h)(2)(i)(A).]
- ii. _____ **Limited information for identification and location purposes.** A covered entity discloses protected health information in response to a law enforcement official's request for such information for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person, *and*
 - 1. The information disclosed is limited to the following
 - a. Name and address;
 - b. Date and place of birth;
 - c. Social security number;
 - d. ABO blood type and rh factor;
 - e. Type of injury;
 - f. Date and time of treatment;
 - g. Date and time of death, if applicable; *and*
 - h. A description of distinguishing physical characteristics.
 - 2. The information does not include, for purposes of identification or location, any protected health information related to the individual's DNA or DNA analysis, dental records, or typing, samples or analysis of body fluids or tissues.
- iii. _____ **Victims of a crime.** Except as required by law or as permitted by other, a covered entity discloses protected health information in response to a law enforcement official's request for such information about an individual who is, or is suspected to be, a crime victim, *if*:
 - 1. The individual agrees to the disclosure; *or*
 - 2. The covered entity is unable to obtain the individual's agreement because of incapacity or other emergency circumstances, provided that (a) the law enforcement official represents that such information is needed to determine whether a violation of law by a person other than the victim has occurred, and such information is not intended to be used against the victim; (b) the law enforcement official represents that immediate law enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to

the disclosure; *and* (c) the disclosure is in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

- iv. ____ **Decedents**. A covered entity discloses protected health information about an individual who has died to a law enforcement official for the purpose of alerting law enforcement of the individual's death, and the covered entity has a suspicion that such death may have resulted from criminal conduct.
- v. ____ **Crime on premises**. A covered entity discloses to a law enforcement official protected health information that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the covered entity.
- vi. ____ **Reporting crime in emergencies**. A covered health care provider providing emergency health care in response to a medical emergency, other than an emergency on the provider's premises, discloses protected health information to a law enforcement official and such disclosure appears necessary to alert law enforcement to (a) the commission and nature of a crime; (b) the location of such crime or of the victim(s) of such crime; and (c) the identity, description, and location of the perpetrator of such crime.

Note: If a covered health care provider believes that the medical emergency is the result of abuse, neglect or domestic violence, this Section does not apply and any disclosure must be subject to Section I.c (above).
- g. ____ **Uses and Disclosures About Decedents**. A covered entity may disclose protected health information in *one* of the following situations:
 - i. ____ The covered entity discloses protected health information to a coroner or medical examiner for the purpose of (a) identifying a deceased person, (b) determining a cause of death, or (3) performing other duties as authorized by law;
 - ii. ____ The covered entity performs the duties of a coroner or medical examiner and uses the protected health information for the purpose of (a) identifying a deceased person, (b) determining a cause of death, or (3) performing other duties as authorized by law; **or**
 - iii. ____ The covered entity discloses protected health information to funeral directors as necessary to carry out their duties with respect to the decedent. *Note:* When necessary, the information may be disclosed prior to, and in reasonable anticipation of, the individual's death.
- h. ____ **Uses and Disclosures for Cadaveric Organ, Eye or Tissue Donation Purposes**. A covered entity may use or disclose protected health information to an entity engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye, or tissue donation and transplantation.
- i. ____ **Uses and Disclosures for Research Purposes**. A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, if *each* of the following conditions are satisfied:
 - i. ____ The covered entity obtains documentation that an alteration to or waiver, in whole or in part, of an individual authorization has been approved by *either*
 - (a) An Institutional Review Board; or

- (b) A privacy board that:
- _____ Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;
 - _____ Includes at least one member who is not affiliated with the covered entity, or with any entity conducting or sponsoring the research, and not related to any person who is so affiliated; *and*
 - _____ Does not have a member participating in a review of any project in which the member has a conflict of interest.
- ii. _____ The documentation of approval of an alteration or waiver must include *all* of the following:
- _____ A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved;
 - _____ A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:
 - (a) The use or disclosure of protected health information involves no more than minimal risk to the individuals;
 - (b) The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;
 - (c) The research could not practicably be conducted without the alteration or waiver;
 - (d) The research could not practicably be conducted without access to and use of the protected health information;
 - (e) The privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to the anticipated benefits and the importance of the knowledge that may reasonably be expected to result from the research;
 - (f) There is an adequate plan to protect the identifiers from improper use and disclosure;
 - (g) There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research; unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and
 - (h) There are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity (except as permitted by law or this subsection).
 - _____ A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or privacy board;

_____ A statement that the alteration or waiver of authorization has been reviewed and approved under normal or expedited review procedures, as follows:

- (a) An IRB must follow the requirements of the Common Rule;
- (b) A privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present, and the alteration or waiver must be approved by the majority of the members at the meeting (unless an authorized expedited review procedure is used);
- (c) A privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the information for which use or disclosure is being sought. If the privacy board elects to use an expedited review procedure, the review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board, or by one or more members of the board as designated by the chair;

_____ The documentation of the alteration or waiver of authorization must be signed by the chair or other designee of the IRB or the privacy board, as applicable.

Note: The required documentation may be satisfied by one or more written statements, each signed and dated accordingly. [§ 164.514(h)(2)(i)(B)]

iii. _____ Prior to research, the covered entity obtains from the researcher representations that:

- _____ Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;
- _____ No protected health information is to be removed from the covered entity by the researcher in the course of the review; *and*
- _____ The protected health information for which use or access is sought is necessary for the research purposes.

iv. _____ If the research involves decedent's information, the covered entity obtains from the researcher:

- _____ Representation that the use or disclosure is sought solely for research on the protected health information of decedents;
- _____ Documentation, at the covered entity's request, of the individuals' deaths; *and*
- _____ Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

j. _____ **Uses and Disclosures to Avert a Serious Threat to Health or Safety.** A covered entity may use or disclose protected health information if the following conditions are satisfied:

- i. ____ The covered entity, in good faith and consistent with ethical conduct, believes the use or disclosure:
- ____ Is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public, *and* is to a person(s) reasonably able to prevent or lessen the threat; **or**
 - ____ Is necessary for law enforcement authorities to identify or apprehend an individual
 - (a) where it appears from the circumstances that the individual has escaped from lawful custody; **or**
 - (b) because of a statement by an individual admitting participation in a violent crime that the covered entity reasonably believes may have caused serious physical harm to the victim. **Note:** Use or disclosure of such a statement may not be made if the statement was learned by the covered entity (i) in the course of treatment, counseling, or therapy to affect the propensity to commit the criminal conduct that is the basis for such disclosure; *or* (ii) through the individual's request to initiate or to be referred for the treatment, counseling, or therapy.
- ii. ____ A disclosure made pursuant to an individual's statement admitting participation in a violent crime contains only the statement and the following information:
- (a) Name and address;
 - (b) Date and place of birth;
 - (c) Social security number;
 - (d) ABO blood type and rh factor;
 - (e) Type of injury;
 - (f) Date and time of treatment;
 - (g) Date and time of death, if applicable; and
 - (h) A description of distinguishing physical characteristics.

Note: A covered entity that uses or discloses protected health information pursuant to this section is presumed to have acted in good faith if its belief is based upon the covered entity's actual knowledge or in reliance on a credible representation by a person with apparent knowledge or authority.

- k. ____ **Uses and Disclosures for Specialized Government Functions.** A covered entity may use or disclose protected health information if *one* of the following conditions are satisfied:
- i. ____ **Armed Forces Personnel.** Protected health information of Armed Forces personnel is used and disclosed for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, if the appropriate military authority has published by notice in the *Federal Register* the following information:
- (a) Appropriate military command authorities; *and*

- (b) The purposes for which the protected health information may be used or disclosed.
- ii. _____ **Separation or Discharge.** A covered entity that is a component of the Depts. of Defense or Transportation discloses to the Dept. of Veterans Affairs the protected health information of a member of the Armed Forces upon the individual's separation or discharge from military service for the purpose of determining eligibility for benefits.
- iii. _____ **Veterans.** A covered entity that is a component of the Dept. of Veterans Affairs uses and discloses protected health information to components of the Dept. for the purpose of determining eligibility for benefits.
- iv. _____ **Foreign Military Personnel.** Protected health information of foreign military personnel is used and disclosed to the appropriate foreign military authority for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, if the appropriate military authority has published by notice in the *Federal Register* the following information:
- (a) Appropriate military command authorities; *and*
- (b) The purposes for which the protected health information may be used or disclosed.
- v. _____ **National Security.** Protected health information is disclosed to authorized federal officials to conduct intelligence and other national security activities authorized by the National Security Act.
- vi. _____ **Presidential Protection.** Protected health information is disclosed to authorized federal officials for the provision of protective services the President (or other persons).
- vii. _____ **Medical Suitability Determinations.** A covered entity that is a component of the Dept. of State uses protected health information to make medical suitability determinations, and discloses such determinations to the Dept. of State officials who need such information for the following purposes:
- (a) For the purpose of a required security clearance;
- (b) As necessary to determine availability for mandatory service abroad; *or*
- (c) For a family to accompany a Foreign Service member abroad.
- viii. _____ **Correctional Institutions.** Protected health information of an inmate is used by a covered entity that is a correctional institution, or it is disclosed to a correctional institution or a law enforcement official with lawful custody of such inmate, if the use or disclosure is necessary for:
- (a) The provision of health care to such individuals;
- (b) The health and safety of such individual or other inmates;
- (c) The health and safety of the officers or employees or others at the correctional institution;
- (d) The health and safety of such individuals and officers or other persons responsible for the transporting or transfer of inmates;
- (e) Law enforcement on the premises of the correctional institution; *and*

- (f) The administration and maintenance of the safety, security, and good order of the correctional institution.

Note: An individual is no longer an “inmate” under this provision when released on parole, probation, supervised release, or otherwise is no longer in lawful custody.

ix. _____ **Government Programs.** One of the following is satisfied:

- _____ A health plan that is a government public benefits program discloses protected health information relating to eligibility or enrollment in the health plan to another agency administering a government benefits program, *and* the sharing or maintenance of such information in a single, accessible data system is required or expressly authorized by law; *or*
- _____ A covered entity that is a government agency administering a government benefits program discloses protected health information relating to the program to another covered entity that is a government agency administering a government benefits program, *and*
 - (a) the programs serve the same or similar populations; *and*
 - (b) the disclosure is necessary to coordinate the covered functions of such programs, or to improve administration and management relating to the covered functions of such programs.

- _____ **Disclosures for Workers’ Compensation.** A covered entity may disclose protected health information as authorized by, and to the extent necessary to comply with, workers’ compensation laws.